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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/073,596	05/06/1998	RALPH M. STEINMAN	ARG010RC	9977

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
11/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/073,596	STEINMAN ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *99-101,104-113,116,120 and 142-144* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *99-101,104-113,116,120 and 142-144* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and remarks filed 8/05/08 are acknowledged.

2. Claims 99, 101, 104-113, 116, 120, and 142-144 are pending.

3. As set forth previously, The instant application is a continuation in part of U.S. Application Nos. 07/981,357, filed 11/25/1992, and 07/861,612, filed 4/01/92. However, the applications do not disclose the invention of the instant claims. First note that the method step employed in instant Claim 101 comprising, "treating the tissue source comprising dendritic cell precursors to increase the proportion of dendritic cell precursors", is not found in the '612 application. Further, neither the '612 nor the '357 applications disclose the cells being cultured with an antigen as is recited in the last step of Claims 101 and 120. Finally, neither application discloses a microorganism antigen, in particular a BCG antigen. Accordingly, the benefit of priority to said applications is denied. The priority date of the instant application is the filing date of parent application 08/040,677 which is 3/31/1993.

Applicant's arguments, filed 8/05/08, have been fully considered. In view of Applicant's citing of page 13 to support "treating the tissue source comprising dendritic cell precursors to increase the proportion of dendritic cell precursors", that ground for denying priority has been withdrawn. Regarding the last step of Claims 101 and 120 comprising the cells being cultured with an antigen, Applicant cites pages 21 and 22 of the specification, as well as Examples 2 and 3. The cite at page 21 discloses only the processing of foreign and autoantigens by DCs to retain their immunogenic form. The cite at page 22 discloses the *in vitro* binding of antigens to DCs. Examples 2 and 3 disclose DCs prepared by specific methods which are not the generic methods of the instant claims. Regarding the claims reciting microorganism antigens, specifically BCG, the claims have been canceled, thus, rendering that reason for denying priority moot.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 99, 101, 104-113, 116, 120, and 142-144 stand rejected under 35 U.S.C. 102(a) as being anticipated by Pancholi et al. (1992).

As set forth previously, Pancholi et al. teaches a pharmaceutical composition comprising human dendritic cells (DCs) pulsed with tuberculosis antigens (see particularly page 218, last paragraph).

The reference clearly anticipates the claimed invention.

Regarding product-by-process claims, MPEP 2113 states:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985), and

"The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983).

Applicant's arguments, filed 11/29/07, have been fully considered but are not found persuasive. Applicant again argues that Pancholi et al. is not available as art.

The issue of priority has been addressed in Section 4 above.

Applicant again argues that the DCs of the reference are not the DCs of the claims.

As set forth previously, the mouse DCs of the instant specification cannot be compared to the human DCs of the reference. Further, the experimental methods of the reference are different than are those of the instant specification, e.g., different populations of T cells are employed. Accordingly, no meaningful comparison can be made.

Applicant's arguments, filed 8/05/08, have been fully considered but are not found persuasive. Applicant again argues that the claimed DCs are not the DCs of the reference. In particular Applicant emphasizes that the DC precursors used to produce the mature DCs of the instant claims were cultured in GM-CSF.

It is noted, however, that the instant claims are not drawn to DC precursors, they are drawn to mature DCs. There is no evidence of record that the method of obtaining the DC precursors results in a different mature DC. The reference teaches mature DCs (evidenced by the fact that they "are particularly effective in initiating antigen-specific T-cell responses," Abstract) and thus anticipates the mature DCs of the instant claims. Further, the mouse DCs of the specification merely exemplify the claimed DCs which are *not* limited to mouse DCs. And as set forth above, an attempt to compare the activity of mouse DCs to human DCs, particularly without even performing a side-by-side comparison, is meaningless. Thus, Applicant's assertion that the claimed cells are "more active" than the cells of the reference is not persuasive.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 101, 104-113, 116, and 120 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Steinman et al. (1974, IDS) as evidenced by O'Doherty et al. (1994, IDS).

As set forth previously, Steinman et al. teaches an *in vitro* composition comprising a mature DC (see particularly Materials and Methods). O'Doherty et al. is merely cited to show that the spleen and lymph node preparations of the reference would have included $CD11^+$ mature DCs (see particularly page 492, column 2,last paragraph). As set forth above, the patentability of a product does not depend on its method of production.

Applicant's arguments, filed 8/05/08, have been fully considered but are not found persuasive. Applicant again argues that the use of GM-CSF in the culture of the DC precursors results in "more active" mature DCs.

See the response in the previous paragraph.

Applicant argues that MLR can be used to compare the stimulatory capacity of antigen-presenting cells.

First note that no MLR comparison data has been submitted. Additionally, it is unclear how Applicant could compare data gathered from experiments employing mouse cells to data gathered employing human cells, however, should Applicant submit such data it will be evaluated as best as is possible.

Applicant argues that because a previous rejection (employing Inaba et al. as art) has been withdrawn the instant rejection should also be withdrawn.

Applicant is advised that the previous rejection was withdrawn because an objective and quantifiable difference between the DCs of the prior art and the DCs of the instant claims was established (the inability of the DCs of Inaba et al. to capture antigen after several days of culture). No such objective and quantifiable difference have been established here.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, Ph.D. can be reached on (571) 272-0878.

11. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/G.R. Ewoldt/
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